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AmCad BioMed Corporation
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K122536
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510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is submitted as part of the Premarket Notification in compliance with requirements of CFR Part 807, Subpart E and Section 807.92

5.1 Identification of Submitter:

Submitter:	AmCad BioMed Corporation
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Manufacturer:	AmCad BioMed Corporation

OCT 0.3 2013

US Agent and Contact:	Chiu S. Lin, Ph.D.
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Date prepared: August 17, 2012

5.2 Identification of Product

Device Trade Name:	AmCAD-UT® Detection 2.0
Common and Usual Name:	Computer-Assisted Detection (CAD) Device
Device Classification Name:	Picture Archiving and Communications System

Regulation Number:	21 CFR 892.2050
Classification Product Code:	90 LLZ
Classification:	Class II
Classification Panel:	Radiology Devices
Manufacturer:	AmCad BioMed Corporation

5.3 Predicate Device

This subject software medical device is substantially equivalent to the devices listed below:

Model:	Q LAB Software
Manufacturer:	Philips Medical System Company
510(k) Number:	K021966, cleared on July 2, 2002

Model:	B-CAD System, Version 1.0
Manufacturer:	Medipattem Corporation
510(k) Number:	K050846, cleared on May 26, 2005

Model:	ColonCAD API
Manufacturer:	Medicsight PLC
510(k) Number:	K083423, cleared on May 17, 2011

5.4 Device Description

AmCAD-UT® Detection 2.0 is a Windows-based computer-assisted detection (CADe) software application device designed to assist medical professionals in analyzing thyroid ultrasound images of user selected regions of interest (ROI).

The device uses statistical pattern recognition and quantification methods to perform analytical function of images. For thyroid ultrasound, these pattern recognition and quantification methods are used by a medical professional to analyze DICOM/JPEG/Bitmap compliant thyroid ultrasound images.

The software application consists of proprietary software developed by AmCad BioMed Corporation. The software is a Windows-based that may be installed on a standalone PC or review station. AmCAD-UT® Detection 2.0 user interface is designed to follow typical clinical workflow patterns to process, review, and analyze digital images.

After the initial review of thyroid ultrasound images by the physician, he/she can use AmCAD-UT® Detection 2.0 to analyze the thyroid images for further interpretation. The physician selects an ROI (Region of Interest) to define the initial boundary of the ROI. Once the ROI is confirmed, the physician may process the image for detection and quantification of sonographic characteristics (i.e., hyperechoic foci, echo-pattern, echo-texture, and anechoic areas) by AmCAD-UT® Detection 2.0. The device provides more detailed information with quantification and visualization of the sonographic characteristics of thyroid nodule that may assist physician in his/her complete interpretation.

The software application also automatically generates reports given the user preference inputs (e.g., the nodule size, nodule location and shape, and the presence or absence of the sonographic characteristics) annotated during the image analysis process. A report form has been designed by AmCad to be consistent with the conventional clinical thyroid report form. An output of the report may be viewed and sent to paper printers or saved on the standalone PC or review station as PDF file.

5.5 Indications for Use

AmCAD-UT® Detection 2.0 is a Windows-based computer-assisted detection (CADe) device intended to assist the medical professionals in analyzing thyroid ultrasound images of user-selected regions of interest (ROI). After the initial review of the ultrasound images by the physicians, the device further provides detailed information with quantification and visualization of sonographic characteristics of thyroid nodules. The device is intended for use on Philips HDI5000 images of discrete thyroid nodules larger than 1cm, for which a biopsy has been recommended. The device performance has been validated on images collected from Philips HDI5000 with a 5-12MHz multi-frequency probe.

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5.6 Comparison with Predicate Devices

AmCAD-UT® Detection 2.0 is substantially equivalent to Q LAB Software with a general intended use for viewing and quantifying ultrasound image data. AmCAD-UT® Detection 2.0 is also substantially equivalent to B-CAD, version 1.0 and ColonCAD API as being Computer-Assisted Detection software device to assist the physicians in clinical practice. The standalone and clinical reader performance assessment of AmCAD-UT® Detection 2.0 are substantially equivalent to the standalone performance assessment and clinical MRMC reader study of ColonCAD API. Minor technological characteristics differences do not raise any new questions of safety and effectiveness. Thus, AmCAD-UT® Detection 2.0 is substantially equivalent to the Q LAB Software generally intended for viewing and quantifying ultrasound image data and substantially equivalent to the B-CAD System and ColonCAD API as the Computer-Assisted Detection device intended to assist the physicians in clinical practice.

The comparison table between our device and the predicate devices is provided below:

	AmCAD-UT® Detection 2.0	**B-CAD System Version 1.0**	**ColonCAD API**	**Q LAB Software**
Manufacturer	AmCad BioMed Corp.	Medipattem Corp.	Medicsight PLC	Philips Medical System Company
510(k) Number	K122536	K050846	K083423	K021966
Device Common Name	Computer-Assisted Detection (CADe)	Same	Same	Picture Archiving and Communications Systems Workstation
Regulation Number	21 CFR 892.2050 - Class II	Same	Same	Same
Regulation Name	Picture archiving and communications system	Same	Same	Same
Product Code	LLZ	LLZ	NWE	LLZ

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	AmCAD-UT® Detection 2.0	B-CAD System Version 1.0	ColonCAD API	Q LAB Software
Intended Use	AmCAD-UT® Detection 2.0 is intended to assist the medical professionals in analyzing thyroid ultrasound images of user-selected regions of interest (ROI). After the initial review of the ultrasound images by the physicians, the device further provides detailed information with quantification and visualization of sonographic characteristics of thyroid nodules.	The B-CAD System provides viewing and post-acquisition image analysis of user-selected regions of interest on breast ultrasound images.	The Medicsight ColonCAD API is intended to be used on patients referred for a CT colonography (CTC) examination, as an overlay tool to prompt the radiologist to colonic findings that have been identified by the device. The CAD can assist radiologists after they have made an initial review of all the colonography image data, supporting their evaluation ("second read")	The Q LAB is a software device designed to view and quantify the ultrasound image.
Indications for Use	AmCAD-UT® Detection 2.0 is a Windows-based computer-assisted detection (CADe) device intended to assist the medical professionals in analyzing thyroid ultrasound images of user-selected regions of interest (ROI). After the initial review of the ultrasound images by the physicians, the device further provides detailed information with quantification and visualization of sonographic characteristics of thyroid nodules.	B-CAD is a computer-aided detection (CAD) software application designed to assist radiologists to analyze breast ultrasound images. B-CAD automatically segments and classifies shape and orientation characteristics of user-selected regions of interest (ROI). The software allows the user to annotate, tag, measure, and automatically record selected views. The	The Medicsight ColonCAD API is designed to assist radiologists in the detection of colorectal polyps during review of digital images derived from CT colonography. In other words, it provides post-acquisition image analysis of CT colonogrpahy images which is indicated to assist the radiologist in the detection of colorectal polyps.	The Q LAB Quantification software is a Windows 2000/Windows XP software application package. It is designed to view and quantify image data acquired on Philips Medical Systems ultrasound products.

	AmCAD-UT® Detection 2.0	B-CAD System Version 1.0	ColonCAD API	Q LAB Software
	The device is intended for use on Philips HDI5000 images of discrete thyroid nodules larger than 1cm, for which a biopsy has been recommended. The device performance has been validated on images collected from Philips HDI5000 with a 5-12MHz multi-frequency probe.	software automatically generates reports from user inputs annotated during the image analysis process. An output may be viewed and sent to standard film or paper printers or sent electronically to an intranet web server or other DICOM device. The software may retrieve archived reports from a web server or other DICOM device. B-CAD includes the option to add annotations based on the ACR-BI-RADS® Breast Imaging Atlas. In addition, the report form has been designed to support compliance with the ACR-BI-RADS® Ultrasound Lexicon Classification Form. When interpreted by a skilled physician, this device provides information that may be useful in screening and diagnosis. Patient management decisions should not be made		

	AmCAD-UT® Detection 2.0	B-CAD System Version 1.0	ColonCAD API	Q LAB Software
		solely on the results of B-CAD analysis. The ultrasound images displayed on B-CAD must not be used for primary diagnostic interpretation.		
Functional Capability of Image Processing	AmCAD-UT®. Detection 2.0 analyzes the user-selected regions of interest (ROI) of thyroid ultrasound image for the detection and quantification of sonographic characteristics (hyperechoic foci, echo-pattern, echo-texture and anechoic areas). The device further provides detailed information with visualization of sonographic characteristics of thyroid nodules.	B-CAD automatically segments and classifies shape and orientation characteristics of user-selected regions of interest (ROI) of breast ultrasound images.	The device highlights the potential polyps (of the colon) in 2D and 3 D image views. The results are displayed in the form of "CAD marks" on or near the potential polyps	The Q LAB software provides a means of opening and displaying (ultrasonic) image files, creating AVI and BMP files from the image data displayed by the software, quantifying the image data using a plugin module designed to operate with the core engine of the software, performing an automatic distance measurement of the intima media thickness of an artery represented in the image file data, creating region of interest figures overlaid on the image data displayed by the software, analyzing the content of the image data contained within the ROI figure, presenting the ROI data in an XY

	AmCAD-UT® Detection 2.0	B-CAD System Version 1.0	ColonCAD API	Q LAB Software
				graphic format, performing a curve fit operation on a data set generated by the ROI analysis software, and exporting the data generated by the plugin modules in a form accessible to the end user.
Reading Paradigm	For use as "second detector" meaning that the function of AmCAD-UT® Detection 2.0 is to provide quantification and visualization of sonographic characteristics after physicians' initial review of the images.	Same	Same	The device provides the functions of viewing and quantifying image data as a "Quantification Software" to the physician in analyzing the ultrasound image.
Output Generated by the CAD Device	The image can be annotated with the detected sonographic characteristics and be recorded by the device. The software also automatically generates reports given the user preference inputs in the analysis process.	The user may select any view for further analysis of anatomy and pathology. The software allows the user to annotate, tag, measure, and automatically record selected view. Results of the analysis are displayed on the monitor and may be selected by the user for automated reporting.	Not known	The software can export the data generated by the plugin modules in a form accessible to the end user.
Type of Film to be Processed by the device	Digital ultrasound image	Digital ultrasound image	Digital CT colonography image	Digital ultrasound Image

	AmCAD-UT® Detection 2.0	B-CAD System Version 1.0	ColonCAD API	Q LAB Software
Software Design	Based on Statistical Pattern Recognition and Quantification method	Based on Mutivariate Pattern Recognition method	Based on Mathematical Image Processing Techniques	Not known
Ground Truth Establishment	The ground truth to be established for performance studies of the device includes the ROI, the presence of each sonographic characteristic, and the surgical pathology examination result.	Not known	Not known	Not known
Platform	Window-based	Window 2000/XP, DICOM compatible	Not known	Windows 2000/XP
Operating System	Standard PC or review station	Same	Not known	Same
Clinical Application	Thyroid cancers	Breast cancers	Colon cancers	Not specified; for general intended use
Image Type	Ultrasound Image	Same	CT image	Ultrasound Image
Image Format	DICOM3.0, Bitmap, JPEG	DICOM3.0	DICOM 3.0	Image data acquired on Philips Medical Systems ultrasound products
ROI Quantification	Yes	Yes	No	Yes
Automatically Generating Report	Yes	Yes	Not known	Not known
Report Storage	Paper printers, Local disk	Standard film, paper printers, web server, other DICOM device	Not known	Not known
Performance Testing Data to Support SE Determination	Results from standalone performance testing and clinical performance testing (MRMC	From the 510(k) Summary that is available on the FDA database, it appears that no data from	Standalone performance assessment, and clinical MRMC study	From the 510(k) Summary that is available on the FDA database, it appears that no data from

	AmCAD-UT® Detection 2.0	B-CAD System Version 1.0	ColonCAD API	Q LAB Software
	study)	standalone performance testing and reader performance testing were submitted.		standalone performance testing and reader performance testing were submitted.

5.7 Performance Standards

No applicable FDA performance standards have been issued under the authority of Section 514.

5.8 Software

Software development for the AmCAD-UT® Detection 2.0 follows documented processes for software design, verification and validation testing. A risk assessment has been completed to identify potential design hazards that could cause an error or injury based on the use of the quantification results. Appropriate steps have been taken to control all identified risks for this type of image viewing and quantification device.

5.9 Summary of Performance Data to Support Substantial Equivalence

AmCad BioMed Corporation has conducted standalone and clinical reader performance studies to validate and assess the performance of the AmCAD-UT® Detection 2.0 for its intended use. The standalone studies include the detection accuracy testing, reproducibility testing, and algorithm stability testing.

The intended use of the AmCAD-UT® Detection 2.0 was validated in a clinical (MRMC) study. The results of the MRMC study demonstrated that the physician reading thyroid nodule sonography images with the assistance of AmCAD-UT® Detection 2.0

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can enhance their ability in analyzing the sonographic characteristics and has led to a significant increase in effectiveness of making clinical judgment.

5.10 Conclusions

The intended use of AmCAD-UT® Detection 2.0 as a CAD device is equivalent to the predicate devices in that it views, analyzes, quantifies, and visualizes the user selected radiologic images that may reveal abnormalities during analysis of patient radiologic images by the intended user. Minor technological characteristics differences do not raise any new questions of safety and effectiveness. Thus, AmCAD-UT® Detection 2.0 is substantially equivalent to the predicate devices as the Computer-Assisted Detection (CAD) device intended to provide viewing and post-acquisition analysis functions for assisting the physicians in clinical practice.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 3, 2013

AmCad BioMed Corporation
% Chiu S. Lin, Ph.D.
President
Lin & Associates, LLC
9223 Cambridge Manor Court
POTOMAC MD 20854

Re: K122536
Trade/Device Name: AmCAD-UT® Detection Model 2.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: August 15, 2013
Received: August 16, 2013

Dear Dr. Lin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

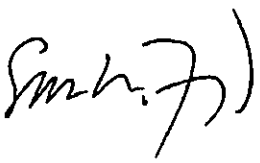
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122536

Device Name: AmCad-UT® Detection 2.0

Indications for Use:

AmCAD - UT® Detection 2.0 is a Windows - based computer - assisted detection (CADe) device intended to assist the medical professionals in analyzing thyroid ultrasound images of user - selected regions of interest (ROI). After the initial review of the ultrasound images by the physicians, the device further provides detailed information with quantification and visualization of sonographic characteristics of thyroid nodules. The device is intended for use on Philips HDI5000 images of discrete thyroid nodules larger than 1cm, for which a biopsy has been recommended. The device performance has been validated on images collected from Philips HDI5000 with a 5 - 12MHz multi - frequency probe.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) ___K122536___